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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,774	06/14/2001	Michael E. Houston	003592-007	9292

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EXAMINER	
FIELD, TAMMY K	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/882,774	HOUSTON ET AL.	
	Examiner	Art Unit	
	Tammy K. Field	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *16-20,27-34 and 42-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15, 21-26, 35-41 and 57* is/are rejected.

7)☒ Claim(s) *1,2 and 14* is/are objected to.

8)☒ Claim(s) *1-57* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/27/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (Claims 1-27, and 57) and species election, a) Pneumococcal surface protein A received in the Office March 8, 2003 is acknowledged. The traversal is on the ground(s) that Group IV (Claims 35-41) is drawn to vaccine compositions comprising the peptide of claim 1. Upon careful consideration, this is found persuasive (in part) because Groups I and IV are both drawn to the peptide of claim 1. Further consideration of Group I identifies additional independent and distinct methods (Claims 16-20 and 27). Thus, a upon a phone interview with Attn. Ping Hwung on March 26, 2004 a provisional election was made with traverse combining Group I (in part) and Group IV (Claims 1-15, 21-26, 35-41, and 57).

Claims 16-20, drawn to a method of making a peptide of formula 1(now Group IX), and Claim 27, drawn to a method of eliciting an immune response (now Group X) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group of invention, there being no allowable generic or linking claim. Further restriction of group I (product(s)/composition(s)) and Groups IX (method of making peptide) and X (method of using peptide) is required because the peptide of formula 1 can be alternatively obtained from nature and may be used alternatively in monoclonal antibody production. Therefore, restriction is deemed proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of

the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The June 23, 2000 date of provisional application 60/211892 will be used for purposes of prior art.

Information Disclosure Statement

3. The information disclosure statement(s) filed September 27, 2001 has been considered. An initialed copy is enclosed.

Specification

4. The disclosure is objected to because of the following informalities:

a. Beginning on page 10 and continuing throughout the specification, using the alphabetical letters of "A", and "D" in formula 1 are confusing as they are also identified in the specification at page 38 as one letter codes which stand for Alanine (A) and Aspartate (D), respectively.

b. Sequences at page 50, line 20, 58, lines 10-17, etc. in the specification are listed without sequence identifiers.

c. ATCC Culture collections at pages 62, line 8, 63, line 16, etc. are incompletely identified in the specification.

Appropriate correction is required.

Claim Objections

5. Claims 1-2, and 14 are objected to because of the following informalities: Using the alphabetical letters of "A", and "D" are confusing as they are also well known as letter codes which stand for Alanine (A) and Aspartate (D).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 14, and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the claims is not as precise as the subject matter permits such that one may reasonably know the metes and bounds of the claims and bounds of the claimed subject matter. The claims are indefinite in the recitation of "derivative" (claims 1 and 14) and "protein" (claim 57) because it is unclear from the specification what applicant intends. Clarification is required in order to overcome this rejection.

which depends from claim 8

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-15, 21-26, and 35-41, and 57 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Briles, D.E. *et al.* 1997. (W0 97/09994).

The claims are drawn to a synthetic peptide of formula I: $(AXXDXXX)_n$ wherein $n \geq 1$, A = Ile, Leu, Val, or derivative thereof and D = Leu, Ile, Val, or derivative thereof, X residues are amino acids that are solvent exposed in a coiled-region of the protein, more specifically Pneumococcal surface protein A, the peptide comprising additional amino acids at the C-terminus and/or N-terminus of the peptide comprising SEQ ID: 5 and at least one X is replaced with a charged amino acid residue. Subsequent claims are drawn to the compositions and vaccines of formula I.

Briles, D.E. *et al.* teach a panel of Pneumococcal surface A's (pspAs) with 3' and 5' α helical coiled-coil region sequences of the native protein from different strains of *Streptococcus pneumoniae* at Example 6, page 99, paragraph 1. Briles, D.E. *et al.* further teach pspAs at Example 6, page 108A, paragraph 4 and in the sequence listing of Bg973c at Fig. 13 (Sheet 5) at residue 36 extending to residue 58, *i.e.*, ...EELSDK<u>IDELDAEIAKLEKD</u>VED...(underlined regions indicates inherently two repeats of the peptide of formula I with partial flanking C-terminus and N-terminus residues of the peptide) wherein n = 2, and bolded letter symbols indicate A = Ile(I) and D = Leu(L), and X residues Asp(D), Glutamate (E), and Lysine(K) are charged wherein sets of X residues are from the same epitope of a single protein, Bg973c that has 90.8% sequence identity to instant claim 12's SEQ ID:5 (GenCore version 5.1.6 sequence search result 1). Briles, D.E. *et al.* also teach the pspA's are part of a highly immunogenic area of the epitopic α helical coiled-coil region sequence eliciting the major protection component of

their Pneumococcal extracts at pages 69L-69M. Briles, D.E. *et al.* further teach a pspA recombinant strain RCT123 (inherently epitopic amino acids are from different strains of microorganism), from parent strain BG8743 (Table 1, page 55A) comprising at least one peptide of formula I (residues 42-55) at Fig. 13 (Sheet 5, 14/83).

As to claims 21, 26, 35, 38-41 containing recitations of the intended use of the claimed composition(s), the purpose(s) must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

In the alternative, the limitation such as in Claim 57, wherein the peptide of formula I comprises stabilizing the peptide through the formation of lactam bridges is viewed as a limitation of optimizing experimental parameters.

The teachings of Briles, D.E. *et al.* are in an analogous field of endeavor and it would have been prima facie obvious to one having ordinary skill in this art at the time the invention was made to use the peptides of Briles, D.E. *et al.* in instant composition(s). The motivation for doing what Applicants have claimed is present in the peptides of the prior taught by Briles, D.E. *et al.*

8. Since the office does not have the facilities for examining and comparing applicants' detection and diagnosis methods with the methods disclosed in the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed method and the methods

of the prior art (*i.e.* that the methods of the prior art does not possess the same material structural and functional characteristics of the claimed methods). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald *et al.*, 205 USPQ 594.

Conclusion

9. No claims are allowed.

10. The prior art of record and not relied upon is considered pertinent to applicant's disclosure:

d. Becker, *et al.* (US Patent 668516) teach peptides each with 90.8% sequence identity to formula I peptide in sequences 1 - 3.

e. Briles, D.E. *et al.* (US Patent 5955089) teach a peptide with 90.8% sequence identity to formula I peptide in sequence 9.

f. Houston, M.E. *et al.* 1998. (J. Peptide Research 52(2) : 81-88) teach lactam formations in antimicrobial cationic peptides.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammy K. Field whose telephone number is (571) 272-0856. The examiner can normally be reached on Monday-Friday from 7am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (571) 272- 0864.

Papers relating to this application may be submitted to Technology Center 1600 Group 1640 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov./. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tammy K. Field
April 16, 2004

L. R. Smith
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